**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 23, 2015

Terumo BCT, Inc.
Nicholas Wong
Regulatory Affairs Specialist
10811 West Collins Avenue
Lakewood, CO 80215-4440

Re: K141938
Trade/Device Name: Spectra Optia Apheresis System
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKN
Dated: February 5, 2015
Received: February 6, 2015

Dear Nicholas Wong,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141938

Device Name
Spectra Optia Apheresis System

Indications for Use *(Describe)*

The Spectra Optia Apheresis System, a blood component separator, may be used to perform therapeutic plasma exchange.

The Spectra Optia Apheresis System, a blood component separator, may be used to perform Red Blood Cell Exchange (RBCX) procedures for the transfusion management of Sickle Cell Disease in adults and children.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 7 510(K) SUMMARY

| | |
|---|---|
| **Owner/Manufacturer:** | Terumo BCT<br>10811 W. Collins Avenue<br>Lakewood, Colorado 80215<br>877-339-4228 |
| **Contact Person:** | Nicholas Wong<br>Regulatory Affairs Specialist |
| **Date of Preparation:** | March 20, 2015 |
| **Trade Name of Device:** | Spectra Optia® Apheresis System |
| **Common Name:** | Apheresis Device or System |
| **Classification Name:** | Automated Blood Cell Separator, Therapeutic |
| **Classification Regulation:** | Unclassified |
| **Product Code:** | LKN |
| **Predicate Device:** | Spectra Optia Exchange Set (K071079, K132429) |

**Device Description:** The Spectra Optia Apheresis System is comprised of three subsystems: the apheresis machine (or equipment), embedded software, and a single-use disposable blood tubing set. The modifications described in this submission enhance the disposable set's manufacturability and usability during therapeutic plasma and red blood cell exchange procedures.

*Spectra Optia Machine and Embedded Software*: The Spectra Optia Apheresis System is an automated, centrifugal, blood component separation device that uses pumps, valves and sensors to control and monitor a disposable, plastic extracorporeal circuit, during therapeutic apheresis procedures. The system's embedded software controls pump flow rates and centrifuge speed to establish and maintain the required plasma/cellular interface, and ensure patient safety.

*Disposable Blood Tubing Set*: The disposable Spectra Optia Exchange Set (Catalog No. 10220) is provide sterile and is intended for single-use only. The set is invasive, in that patients are connected to the disposable using a needle or other blood access device (catheter, port, etc.). The patient's blood comes into direct contact with the biocompatible plastics that comprise the set. Key components of the set include the [1] centrifuge channel (inside which the patient's blood is separated into its components), [2] the plastic cassette that integrates the tubing/defines the fluid path for ease of installation and use and, [3] the pre-attached waste bag into which the diseased

blood component is collected. Modifications to the FDA-cleared Exchange Set are described in the following table.

**Table 1: Modifications to the Disposable Spectra Optia Exchange Set**

| | Modification | Reason for Change | Functional Impact of Change |
|---|---|---|---|
| 1 | The set's current **Vent Bag** will be replaced with a slightly larger bag. | Ease of Manufacturing – almost all other Terumo BCT-manufactured disposable sets are made with the larger Vent Bag. | None – the original and new vent bags are functionally equivalent. |
| 2 | A **Needleless Injection Port** will be provided on the set's Return Line. | Enhance system/set usability, by reducing the opportunity for needle-stick injuries. | None – like the original return line injection port, the needleless injection port allows the operator to sample or administer fluids during the procedure. |
| 3 | A **Sterile Barrier (IV) Filter** will be added to the set's Anticoagulant (AC) Line. | The filter allows air from an empty AC container to be vented, improving the system's usability. | Air from an empty AC container does not enter the centrifuge and cause an unwanted system alarm. |

**Intended Use/Indications for Use:**

**Intended Use:**
The Spectra Optia Apheresis System, a blood component separator, may be used to perform therapeutic plasma and red blood cell exchange procedures.

**Indication for Use:**
The Spectra Optia Apheresis System, a blood component separator, may be used to perform therapeutic plasma exchange.

The Spectra Optia Apheresis System, a blood component separator, may be used to perform Red Blood Cell Exchange (RBCX) procedures for the transfusion management of Sickle Cell Disease in adults and children.

**Technological Comparison:** The modified Spectra Optia Exchange Set does not in any way change the system's fundamental scientific technology or principle of operation; that is, the separation of blood into its components using centrifugation.

**Substantial Equivalence:** The modified disposable set's substantial equivalence to its predicate is summarized below.

TERUMOBCT

Spectra Optia® Apheresis System
**Spectra Optia Exchange Set, Catalog No. 10220**
K141938

**Table 2: Key Similarities – Unmodified vs. Modified Spectra Optia Exchange Set**

| *Attribute* | | *Comparison* |
|---|---|---|
| **1** | **Intended Use / Labeling** | The modifications to the Spectra Optia Exchange Set do not change the Spectra Optia Apheresis System's intended use. The disposable set's Instructions for Use have been modified to describe the proper use of the new needleless injection port. |
| **2** | **Essential Technology** | The modifications to the disposable blood tubing set do not alter the Spectra Optia System's essential technology. |
| **3** | **Materials** | The Spectra Optia Exchange Set, in both its original and modified configurations, is comprised of well-characterized, biocompatible materials. |
| **4** | **Sterility / Manufacturing** | The original and modified Exchange Sets are sterilized in the same way and are manufactured using almost identical processes. Manufacturing procedures have been modified to reflect the use of the larger vent bag, the addition of the needleless access port/manifold to the set's Return Line, and the new IV filter on the AC line. |
| **5** | **Clinical Performance** | Comprehensive verification testing confirmed that the new needleless access port performed as designed. A broad range of activities were conducted, including mechanical testing, biocompatibility testing, and evaluations of the modified Exchange Set's sterility, packaging and shelf life.<br><br>Simulated-use testing demonstrated that the IV Filter on the AC Line and the Larger Vent Bag are functionally compatible with the system's embedded software and that the linear line length of air in the AC Line during an AC bag empty event is reduced when the IV Filter is installed. Specifically, no air was able to travel past the IV Filter, using the modified Exchange Set, during an "AC Bag Empty Event". For the unmodified set, the length of air measured in the AC line averaged 13.3 inches (S.D.: 1.3 inches), compared to 0 inches in the modified set. |